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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,273	04/10/2001	Roland Cherif-Cheikh	05339-014003	2832

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DAWN JANELLE AT
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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/832,273	Applicant(s) CHERIF-CHEIKH, ROLAND	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: the brief description of the drawings should indicate Fig. 18A and Fig. 18B. (While Applicant indicates "right" and "left" in the brief description of the drawings for figure 18, the drawings are actually labeled Fig. 18A and B and the specification should be amended to have a brief description of the drawings for Fig. 18A and Fig. 18B.)

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-8 and 22-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,776,107. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant recites in the present claims "wherein said liquid and said dry drug composition (20) are combined in said housing (10) prior to injection" in claim 6, line 5-6, which encompasses an embodiment wherein the liquid and dry drug have been combined *before* providing them inside the injection device and are still combined while still in the injection device. That is, because Applicant has not recited how the liquid and dry drug composition are combined, or alternatively that the liquid and dry drug composition are separated in the injection device and subsequently combined in the injection device, the term "combined" is interpreted to mean that the liquid and dry drug are provided as a combination or mixture in the injection device. U.S. Patent No. 5,776,107 (hereinafter Patent '107) recites an injection device having a housing that is configured to contain a liquid or semi-solid composition (see preamble), and thus, Patent '107 is capable of containing a liquid and dry drug composition that is combined in the housing, i.e., that is provided as a combination in the housing. The remaining limitations of Applicant's current claims are all otherwise recited in the claims of Patent '107. (It appears that an amendment to the claims to recite that the liquid and dry drug composition are separated in the injection device and subsequently combined in the injection device would overcome this rejection.)

(It is also noted that because the *preamble* of claim 6 recites a liquid and semi-solid composition, but the *body* of the claim does not mention a semi-solid *per se*, the liquid and dry drug composition being combined in the housing is thus interpreted by Examiner as meaning that the liquid and dry drug composition forms a semi-solid composition.)

Claim 27 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,776,107, in view of Perouse, 6,110,147.

Claim 27 depends from claim 6 (which has been discussed above), and claim 27 further recites that the septum plunger contains a bore which the needle pierces. This limitation is not recited in Patent '107.

However, Perouse teaches an element disclosed as a "front plunger 62" that, in operation, is punctured by the proximal end of the needle to allow for the composition inside the injection device to be injected to a subject (see figs. 1-4) and col. 4, lines 9-10.) Figures 1-4 also show that the front plunger has a bore through which the proximal end of the needle will go through. Perouse that the front plunger has a transverse partition which can be punctured and which is surrounded by a cylindrical lateral wall which is equipped with peripheral ribs in order to guarantee liquid tightness and gas

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tightness between itself and the inner lateral wall of the injection device (col. 4, lines 10-15).

The front plunger disclosed by Perouse has the structural and functional characteristics of a septum plunger and thus is considered to be a septum plunger, even if the prior art does not utilize this term to describe it. While Perouse does not further give specific details in the written description of the bore, the drawings however are part of the disclosure and the skill artisan would recognize that the bore facilitates the insertion of the proximal end of the needle through the front plunger, as disclosed in the drawing in figures 1-4, illustrating the operation of the injection device. It would have been obvious to one of ordinary skill in the art to provide a bore as taught by Perouse in the septum plunger of Patent '107 because Perouse discloses a septum plunger with a bore and illustrates that this bore facilitates insertion of the proximal end of a needle, as would be desirable for administering the composition inside the injection device to a subject. Alternatively, it would have been obvious to the skilled artisan to provide a septum plunger as taught by Perouse (at reference 62), as the septum plunger in Patent '170, because Perouse teaches that the septum plunger, as a whole, including the peripheral ribs, provide the benefit of guaranteeing liquid tightness and gas tightness between itself and the inner lateral wall of the injection device, while allowing for the septum plunger to move and be pierced by the proximal end of the needle for delivery of the composition within the injection device. Thus, because the Perouse plunger contains a bore, providing the Perouse plunger as the septum plunger recited in Patent '170 provides a bore in the septum plunger in Patent '170.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's argument regarding the previous obviousness double patenting rejections were found to be persuasive in that Examiner agrees that the prior art in the previous Office action does not teach or suggest a septum plunger that is provided *in addition to* another plunger, wherein the sleeve covers the needle prior to injection and *retracts during injection or insertion* of the needle in a subject, *and contacts* the septum plunger and covers the needle after injection. Scherer et al., 2,460,039, disclose a septum plunger, but do not disclose or suggest that the septum plunger contacts and moves a sleeve, and Patent 5,695,463 discloses moving a sleeve but does not disclose or suggest that it is moved by a septum plunger that is provided in addition to another plunger. Thus, the previous rejection has been withdrawn. However, upon further review, the obviousness double patenting rejections newly stated above are found to be appropriate.

Also, in view of the amendments to the claims, the objections to the claims and the rejections under 112, second paragraph maintained in the previous Office action has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ANN YEN LAM
PATENT EXAMINER